Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

MAR 14 2005

RE: Notification of a structure/function statement on dietary supplement product PROSTATINE, marketed by TOMIL HERB INC.

## Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. § 343(r)(6), notification is submitted for a structure/function statement appearing on the label and/or in labeling of the dietary supplement product PROSTATINE.

NAME / ADDRESS OF DISTRIBUTOR	TOMIL HERB INC
	291 St. Lawrence Dr., Welland
	ON L3C 7H7, Canada
STATEMENT	Herbal tonic supporting prostate and urinary health.*
DISCLAIMER	*This statement has not been evaluated by the Food and Drug Administration. This product is
	not intended to diagnose, treat, cure or prevent
	any disease.
DIETARY INGREDIENTS	European Goldenrod (stern)
	Field Eryngo (root)
	Corn (hair)
,	Echinacea angustifolia (root)
	European Vervain (stem)
	Pumpkin (seed)
	Restharrow (root)
	St. John's Wort (stem)
	Tribulus (stem)
	Uva-Ursi (leaf)
DIETARY SUPPLEMENT PRODUCT NAME	PROSTATINE

The undersigned certifies that the information contained in this notice is complete and accurate, and that TOMIL HERB INC has substantiation that the statement made is truthful and not misleading.

As required, the original and two copies of this notification are enclosed. If you have any questions or need any additional information, please contact the undersigned at (289)-241-3629.

Sincerely,

George Manolov Director of Marketing TOMIL HERB INC

**Enclosures** 

Certified Mail - Return Receipt Requested

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